4 29. (New) The method of Claim 26, 3 wherein the precancerous precursors of prostate adenocarcinoma is prostate intraepithelial neoplasia (PIN).

5 30. (New) The method according to Claim 26, 3 wherein said subject has benign prostatic hyperplasia, or an abnormally high level of circulating prostate specific antibody (PSA).

6 31. (New) The method according to any of Claims 26 1 or 27, 2 wherein said pharmaceutical preparation further comprises a pharmaceutically acceptable carrier.

A 1 7 32. (New) The method according to Claim 31, 16 wherein said carrier is selected from the group consisting of a gum, a starch, a sugar, a cellulosic material, or mixtures thereof.

8 33. (New) The method according to any of Claims 26 1 or 27, 2 wherein said selective estrogen receptor modulator (SERM) is administered subcutaneously, orally, intravenously, intraarterially, intramuscularly, or topically.

9 34. (New) The method according to Claim 33, 8 whereby said subcutaneous administration is by implanting in said subject a pellet containing said pharmaceutical preparation.

10 35. (New) The method according to Claim 34, 9 wherein said pellet provides for controlled release of said pharmaceutical preparation over a period of time.

11 36. (New) The method according to Claim 33, 8 whereby said intravenous, intra-arterial, or intramuscular administration is by intravenously, intraarterially, or intramuscularly injecting in said subject said pharmaceutical preparation in a liquid form.

12 37. (New) The method according to Claim 26, 11 whereby said oral administration is by orally administering to said subject in a liquid or solid preparation containing said pharmaceutical preparation.

13 38. (New) The method according to Claim 27, 12 whereby said topical administration is by applying to skin surface of said subject said pharmaceutical preparation.

14 39. (New) The method according to Claim 26, 13 wherein said pharmaceutical preparation is selected from the group consisting of a pellet, a tablet, a capsule, a solution, a suspension, an emulsion, an elixir, a gel, a cream, and a suppository.

15 40. (New) The method according to Claim 39, 14 wherein said suppository is a rectal suppository or a urethral suppository.

16 41. (New) The method according to Claim 26, 13 wherein said pharmaceutical preparation is a parenteral formulation.

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17 42. (New) The method according to claim 41, 16 wherein said parenteral formulation comprises a liposome comprising a complex of said an selective estrogen receptor modulator (SERM) and a cyclodextrin compound.

18 43. (New) A method of suppressing or inhibiting pre-malignant lesions of prostate cancer of a subject comprising: administering to the subject a pharmaceutical composition comprising an selective estrogen receptor modulator (SERM); and a pharmaceutically acceptable salts, esters, or N-oxides, or mixtures thereof, thereby suppressing or inhibiting the pre-malignant lesions of prostate cancer of the subject.

19 44. (New) A method of treating a subject with pre-malignant lesions of prostate cancer comprising the steps of: administering to the subject, a pharmaceutical composition comprising an selective estrogen receptor modulator (SERM); and a pharmaceutically acceptable salts, esters, or N-oxides, or mixtures thereof, thereby treating the subject with pre-malignant lesions of prostate cancer.

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20 45. (New) The method of any of Claims 43 18 or 44, 19 wherein the pre-malignant lesion is a precancerous precursors of prostate adenocarcinoma.

21 46. (New) The method of Claims 45, 20 wherein the precancerous precursors of prostate adenocarcinoma is prostate intraepithelial neoplasia (PIN).

22 47. (New) The method of Claim 46, 21 wherein the prostate intraepithelial neoplasia is high prostate intraepithelial neoplasia (HPIN).

23 48. (New) The method according to any of Claims 43 18 or 44, 19 wherein said pharmaceutical composition further comprises an acceptable carrier or diluent.

24 49. (New) The method according to Claim 48, 23 wherein said carrier is selected from the group consisting of a gum, a starch, a sugar, a cellulosic material, or mixtures thereof.

25 50. (New) The method according to any of Claims 43 18 or 44, 19 wherein said selective estrogen receptor modulator (SERM) is administered subcutaneously, orally, intravenously, intraarterially, intramuscularly, or topically.

26 51. (New) The method according to Claim 50, 25 whereby said subcutaneous administration is by implanting in said subject a pellet containing said pharmaceutical composition.

27 52. (New) The method according to Claim 50, 25 wherein said pellet provides for controlled release of said pharmaceutical preparation over a period of time.

28 53. (New) The method according to Claim 50, 25 whereby said intravenous, intra-arterial, or intramuscular administration is by intravenously, intraarterially, or intramuscularly injecting in said subject said pharmaceutical composition in a liquid form.

29 54. (New) The method according to Claim 50 25, whereby said oral administration is by orally administering to said subject in a liquid or solid preparation containing said pharmaceutical composition.

30 55. (New) The method according to Claim 50 25, whereby said topical administration is by applying to akin surface of said subject said pharmaceutical composition.

A 1 31 56. (New) The method according to any of Claims 43 18 or 44 19, wherein said pharmaceutical composition is selected from the group consisting of a pellet, a tablet, a capsule, a solution, a suspension, an emulsion, an elixir, a gel, a cream, and a suppository.

32 57. (New) The method according to Claim 56 31, wherein said suppository is a rectal suppository or a urethral suppository.

33 58. (New) The method according to any of Claims 43 18 or 44 19, wherein said pharmaceutical composition is a parenteral formulation.

34 59. (New) The method according to Claim 58 33, wherein said parenteral formulation comprises a liposome comprising a complex of said an selective estrogen receptor modulator (SERM) and a cyclodextrin compound.–

REMARKS

Claims 1-25 were pending in the subject Application. Applicants have hereinabove canceled claims 1-25; and added new claims 26-59. Therefore, Claims 26-59 are now pending.

Applicants note that no amendment made herein are related to the statutory requirements of patentability unless expressly stated herein; and no amendment made was for the purpose of narrowing the scope of any claim, unless Applicants has argued herein that such amendment was made to distinguish over a particular reference or combination of references. Applicants respectfully request entry of the amendment.

Attached hereto is a marked-up version of the changes made to the subject specification and claims by the hereinabove amendment. The attached page is captioned "Version With Markings To Show Changes Made."

REJECTION UNDER 35 U.S.C. 112, First paragraph:

In the Office Action, the Examiner rejected the Claims under 35 U.S.C. 112, first paragraph, as allegedly containing subject matter which was not described in the specification

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